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AQIM Handbook

Appendix C

Trade Articles

Contents

Use this appendix to obtain information and criteria on risk management. Contained here are the:

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AQIM Handbook

Appendix C

APHIS Trade Risk Analysis Position[1]

Introduction

The Animal and Plant Health Inspection Serviced (APHIS) anticipates and responds to U.S. issues that involve animal and plant health, conflicts with wildlife, environmental stewardship, and animal well-being. With our customers and stakeholders, we promote the health of animal and plant resources to facilitate their movement in the global marketplace and to ensure abundant agricultural products and services for American consumers.

An important component of the APHIS mission is to facilitate the safe movement of import and export commodities. APHIS uses risk analysis to make trade decisions in a risk assessment (the scientific evaluation of the biological risks and potential consequences), risk management (a process of determining appropriate mitigation measures to reduce risk), and risk communication (the sharing of risk information). The results of risk analyses provide well supported recommendations to APHIS decision makers to achieve the objective of facilitating safe trade.

The Agreement on Sanitary and Phytosanitary Measure of the General Agreement on Tariffs and Trade requires that countries base their animal, plant, and human health requirements related to trade on relevant international standards. If appropriate standards do not exist, or a country chooses not to use the existing international standards, then the Agreement requires that the regulatory authorities of the importing country base their import requirements on a scientific risk analysis.

Like many in the international trade community, APHIS holds the view that mutually accepted standards will help ensure safe trade that is consistent, fair, enhances economic prosperity and reduces trade tensions. APHIS is committed to an active role in the International Office of Epizootics, the International Plant Protection Convention, and other international standard setting bodies to further the development of risk analysis standards and guidelines.

1 APHIS Trade Committee, Trade Risk Analysis Core Team. 1996

APHIS recognizes that risk analysis is a dynamic process and therefore must retain sufficient flexibility to incorporate scientific advances. APHIS is committed to revising risk analysis procedures, as appropriate, to continually take advantage of the best available science.

The Agreement on Sanitary and Phytosanitary (SPS) Measures of the General Agreement on Tariffs and Trade (GATT) requires members to base their animal, plant, and human health requirements related to trade on an objective analysis of risk. The SPS Agreement also requires that members make their risk analysis procedures transparent and available to other interested members.

To address the issue of transparency under the SPS Agreement, this document provides an overview of the risk analysis process used by the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture.

APHIS has a long history of practical experience and knowledge related to risk analysis. Considerable time and resources have been invested in refining risk analysis models and techniques as well as developing new ones. APHIS also actively supports and participates in international discussions to further the development of risk analysis standards and procedures related to trade.

APHIS and Risk Assessment

Risk analysis, as defined by APHIS, is equivalent to risk assessment as defined in the SPS Agreement. The APHIS risk analysis definition and subsequent explanations provide additional detail and interpretation of the SPS risk assessment definition.

The SPS Agreement defines risk assessment as:

> “The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according the sanitary or phytosanitary measure which might be applied, and of the associated potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins, or disease-causing organisms in food, feedstuffs and beverages."

APHIS defines risk analysis as a process comprised of risk assessment (the scientific evaluation of the biological risks and potential consequences), risk management (a process of determining appropriate mitigation measures to reduce risk), and risk

communication (the sharing of risk information). The results of APHIS risk analyses provide well supported recommendations to APHIS decision makers to achieve the objective of facilitating safe trade.

APHIS believes its definition is fully consistent with the SPS Agreement. The documentation of this process provides risk analysts with guidance in the preparation of recommendations for decision makers and makes the process more transparent to our trading partners.

APHIS Risk Analysis Principles

APHIS recognizes that there are various approaches to risk analysis. The selection of the approach depends on the particular circumstances associated with the commodity and the current pest or disease information.

Regardless of the approach, APHIS believes that a credible risk analysis process must embody the following principles:

- GATT Consistent
- Science-based
- Well-documented
- Flexible
- Open to Review

GATT Consistent

APHIS risk analysts understand and comply with GATT SPS terms and principles and produce Agency recommendations that can withstand ATT/World Trade Organization (WTO) challenges. Compliance with the SPS Agreement also means that APHIS is committed to using relevant standards of the International Office of Epizootics, the International Plant Protection Convention, or other relevant international or regional organizations recognized by the WTO. Alternatives to the standards may be used when supported by objective risk analyses.

Science-based

Data used in APHIS risk analyses are collected and evaluated using the best available scientific methods. Also, APHIS analysts recognize the importance of describing uncertainty and identifying data gaps. APHIS analysts actively solicit input and review from the scientific community to the extent necessary to confirm the scientific integrity of risk analysis.

Well-documented

Data used in the risk analysis are organized, evaluated, and referenced in a systematic manner and in sufficient detail to allow interested parties to understand the process.

Flexible

Because of the pest and disease situations evaluated using risk analysis, methods that apply to one situation may be irrelevant or misleading in evaluating another. While acknowledging that various methods can be used, APHIS analysts are able to articulate the rationale for the choice of a method. Flexibility also means that the risk analysis process is dynamic and able to accommodate new information and technology.

Open to Review

APHIS acknowledges its responsibility to document the risk analysis process and allow interested parties to provide relevant scientific information and comments on the process and results.

Components of the APHIS Process for Risk Analysis

When initiating a risk analysis because action is proposed, such as a commodity importation or other relevant event, APHIS analysis will identify and record background information and situation-specific details, such as the source of the request, the origin, proposed destination, and intended use for the commodity. The analysis then proceeds following the general process outlined below.

Risk Assessment

APHIS defines risk assessment as the evaluation of the likelihood and the biological and economic consequences of entry, establishment or spread of a pest or disease agent within the territory of an importing country. Risk assessments also consider the degree of uncertainty associated with a proposed action.

The degree of uncertainty depends upon the availability and quality of pest/disease data. An agent for which little is known cannot be as precisely assessed as one for which much more relevant information is available. A high degree of biological uncertainty, because of limited scientific information, may justify conservative estimate. However, APHIS also recognized the importance of updating risk assessments as additional scientific information becomes available.

A risk assessment evaluates the unmitigated pest or disease risk in order to determine if there is sufficient risk to warrant mitigation. The focus is on establishing the existence of biological and economic consequences and the likelihood of their occurrence. In many cases, there is broad agreement concerning this risk, negating the need for formal risk assessment.

Formal risk assessments are conducted when the unmitigated risk is not clearly understood to be wither acceptable or unacceptable. These assessments are also important when assumptions concerning the level of unmitigated risk are challenged or when new information concerning the unmitigated risk has been provided. The assessment of risk at this level typically involves the evaluation of origin, commodity, and destination factors.

Origin Risk Factors: The evaluation of the exports are to estimate the likelihood that agents of sanitary or phytosanitary concern are associated with a commodity importation, including:

- Prevalence of a pest or disease agent in the exporting area
- Geographic and environmental characteristics
- Sanitary and Phytosanitary status of the adjoining or neighboring areas
- Trading partners and practices
- Regulatory infrastructure of the exporting country
- Surveillance system(s)
- Previous risk assessments (including foreign country) on commodity and related commodities from the same origin.

Commodity Risk Factors: APHIS analysts consider information about the commodity to estimate the likelihood of introduction of a particular pest or disease agent. Commodity factor include:

- Type of class of commodity
- Nature of raw material used to produce commodity
- Intended use of the product
- Pest or disease agent survival in transit
- Interception data

Destination Risk Factor: An evaluation of the likelihood and consequences of a particular pest or disease agent surviving, multiplying, establishing, and spreading in the territory of the importing country. Destination factors include:

- Distribution of the commodity
- Availability of susceptible host and/or competent vectors
- Geographical and environmental characteristics

Risk Management

APHIS defines risk management as the process of analyzing and recommending options for mitigating pest and disease agents of concern identified through risk assessment.

In determining appropriate levels of protections, the SPS Agreement requires that countries base their animal, plant, and human health requirements on relevant international standards. If an appropriate standard does not exist or a country chooses not to use an existing standard, then the Agreement requires regulatory authorities of the importing country to base their health requirements on a scientific analysis of the risks to animal, plant, or human health and to share information regarding the analyses with interested parties.

The analysis risk mitigation options may vary due to the differing nature of animal, plant, and human health issues.

Consistent with SPS Agreement, APHIS maintains transparent processes for objectively evaluating new risk mitigation alternatives in situations where an international standard may not exist or may not be appropriate. In evaluating these alternatives, APHIS will consider biological as well as economic factors including, but not limited to, potential damage in terms of loss of production or sales in the event of entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost effectiveness of alternative approaches to risk eradication.

APHIS recognizes the responsibility of the exporting country to address the importing country's sanitary and Phytosanitary issues of concern. APHIS approves risk management options based on a comprehensive evaluation of the efficacy and feasibility of the option in reducing the likelihood and magnitude of the biological and economic consequences identified in the risk assessment.

Efficacy: The degree to which a mitigation option reduces the likelihood magnitude of adverse biological and economic consequences is a measure of its efficacy. Evaluating mitigation options for efficacy is an iterative process that involves revisiting risk assessment to determine the degree to which risk is reduced by the implementation of the option. In cases where an acceptable efficacious option exists, the efficacy of new options needs to compare favorable with existing options.

Feasibility: The evaluation of mitigation options for feasibility normally focuses on technical, operational, and economical factors affecting the implementation of mitigation options. It is in this level of evaluation that factors relevant to industry needs and practices are considered, as well as the potential for applying new technologies.

This level of evaluation is a responsibility shared primarily by the exporting country and the commercial sector (industry). APHIS assumes that feasibility has been considered when a risk management proposal is offered by the exporting country. The role of APHIS in this

level of evaluation is to assess whether the exporting country is able to meet its obligations and to ensure that undesirable impacts are not placed upon the United States (e.g. at National level).

APHIS recognizes that information to objectively determine tolerable risk levels may not always be readily available. In accordance with the SPS Agreement, APHIS adheres to the premise that it may be necessary to institute provisional sanitary and phytosanitary measures until scientific evidence can be obtained to justify a different position. APHIS is committed to working with relevant parties to obtain and evaluate this information in a timely manner.

APHIS is committed to ensuring that recommended measure are not more trade restrictive than required to achieve their appropriate level of sanitary and phytosanitary protection.

Risk Communication

APHIS defines risk communication as the process of exchanging information concerning risk with interested parties (e.g. domestic and foreign industry groups, foreign governments, consumer groups, and other interested individuals). This includes the active exchange of information throughout the risk analysis process with involved parties and the communication of the conclusions of risk analyses to all interested and impacted parties. This process includes routine interaction with the scientific community to ensure the validity of scientific data, methods, and assumptions.

When risk analysis is used as a basis for promulgating regulations, APHIS meets risk communication goals and transparency obligations by publishing proposed and final rules in the Federal Register. APHIS demonstrates it commitment to transparency by notifying the WTO of any measure which may affect another country's trade.

New proposed regulatory changes published in the Federal Register specify the risks and the requirements which will be imposed to mitigate the risks. After public comments are received and reviewed a decision is made regarding a final result. If comments and input are compelling enough for APHIS to change its position, the proposed rules will be withdrawn and alternative courses of action may be considered. Both the proposed and final rules explain the factors supporting the Agency's choice of mitigation measures, including the Agency's geological concerns and scientific rationale to support the decision.

Conclusion

APHIS considers the product of risk analysis to be risk-based recommendations. Decision makers take those recommendations into account as well as other factors they may consider relevant.

Appendix C

GATT Agreement on the Application of Sanitary and Phytosanitary Measures[2]

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risk to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Member shall take into account relevant economic factors: the potential damage in terms of loss of productions or sales in the event of the entry; establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.
4. Member should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective minimizing negative trade effects.
5. With the objective achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Member shall cooperate in the Committee, in accordance with paragraphs 1, 2, and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In

2 GATT Agreement, Article 5

developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. [4]Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations, as well as from sanitary or phytosanitary measures applied by other Members. In such circumstance, Member shall seed to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain its exports and the measure is not based on the relevant international standards, guidelines, or recommendations, or such standards, guidelines, or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure